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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,923	09/15/2003	Peter M. Bonutti	2500DV2CN2DV3CN2	2728

7590 08/03/2005

Patent Counsel
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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,923

Applicant(s)

BONUTTI, PETER M.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/24/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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Claims 2-5, 7-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitation in claim 2, line 7-8 that the first aperture of the first inflatable member is configured and dimensioned for slidably receiving a surgical instrument therethrough. As seen in figure 13 of applicant's disclosure, the aperture of the first inflatable member 160 has a diameter that is larger than the diameter of the inner lumen of cannula 154. Although the instrument 166 is capable of contacting and sliding on the inner surface which forms the inner lumen of cannula 154, such contact appears to prevent the instrument 166 from contacting the surface which forms the aperture of the first inflatable member 160 due to its larger diameter. There is no basis in the original disclosure for the term "slidably" in claims 8 and 9 for similar reasons.

Claims 2-5, 7-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. Claim 2 is confusing and inaccurate for the reasons set forth above.

Claims 2, 5, 7-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367). Daniels et al. disclose first tubular member 68 having an open proximal end, first inflatable member 72, second tubular member 16 having an open proximal end and an open distal end defining a bore 18 therethrough (col. 3, lines 18-22) and second inflatable member 30. Daniels et al. fail to disclose the first inflatable member 72 and first tubular member 68 having an open distal end (since guidewire 74 plugs the distal end of the first inflatable member 72 as indicated in col. 4, lines 54-59). However, Kontos et al. teach that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably receive the guidewire instead of being fixed to the guidewire (col. 8, lines 8-19). This arrangement has the self-evident advantage of enabling the position of the tubular member to be adjusted relative to the guidewire. It would have been obvious to make the distal end of the first inflatable member 72 and first tubular member 68 of Daniels et al. open so that they can slidably receive a guidewire so that it too would have this advantage. The slidable guidewire is considered to be the surgical instrument

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referred to in the claim. Movement of the first inflatable member 72 towards the second inflatable member 30 is inherently capable of capturing body tissue therebetween, particularly since the second inflatable member 30 can be as large as 4 cm in diameter as indicated in col. 3, lines 55-59 and since the first inflatable member 72 appears to have a diameter which is comparable to the diameter of the second inflatable member 30 as seen in figure 6.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Evard et al. (4,981,478). Daniels et al. fail to disclose an inner member defining an annular space with the first tubular member. However, Evard et al. teach that a balloon catheter can be constructed with an inner tubular member 13 and outer tubular member 11 with an annular space therebetween (col. 4, lines 19-30). This arrangement has the advantage of enabling inflation fluid to pass through the annular space and a guidewire to slidably pass through the inner tubular member while maintaining a small profile. It would have been obvious to so construct the Daniels et al. first tubular member so that it too would have this advantage.

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Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Mecca (4,690,140). The distal end of first tubular member 68 of Daniels et al., as modified above to be open so that it can slidably receive a guidewire (the claimed surgical instrument) would inherently be capable of receiving an endoscope or laparoscopic instrument since an endoscope or laparoscopic instrument can be as small in diameter as a guidewire. Mecca is cited to support this assertion since it discloses a very thin endoscopic guide member 1 which is broadly an endoscope since it allows viewing into the area (col. 2, lines 10-14 and col. 6, lines 1-9). Note that the surgical instrument itself is not part of the claimed combination.

Applicant's arguments filed June 23, 2005 have been fully considered but they are not persuasive. As to the rejection of claims 2-5, 7-9 and 11-13 under 35 U.S.C. 112, first paragraph, the term "slidably" (claim 2, line 7), by definition, requires the members (i.e. the first aperture and the surgical instrument) to be contact with each other during relative movement of the members. Note that both the first aperture and the first bore are recited as being configured and dimensioned for slidably receiving a surgical instrument in view of the term

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"and" after "the first aperture" and before "the first bore" in claim 2, line 7. As to the combination of Daniels et al. and Kontos et al., the proposed modification of the Daniels et al. device in view of Kontos et al. would not render the Daniels et al. device incapable of being maneuvered from the proximal end of the device since a steerable guidewire could be first inserted into the body to the intended location and the balloon catheter inserted over it and guided (i.e. maneuvered) to the same location as described in col. 8, lines 8-19 of Kontos et al. Alternatively, the guidewire and catheter could be inserted as a unit as described in col. 8, lines 15-19 of Kontos et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
8/2/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731